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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,371	10/03/2003	Benjamin V. Treadwell	030229	4023

26285 7590 03/19/2007
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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,371	TREADWELL, BENJAMIN V.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *6 and 30-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, claims drawn to a composition for attenuating at least one factor involved in the inflammation associated destruction of tissue comprising a first component comprising a long-chain normal primary aliphatic alcohol, and a second component selected from the group consisting of a B12 vitamin, a D vitamin, coenzyme Q, an omega-3 fatty acid and combinations thereof with elected **species** of **triacontanol (**primary aliphatic alcohol); **methylcobalamine** (B12 vitamin); and **Vitamin D3** (D vitamin) is acknowledged. Accordingly, claims 6 and 30-64 are withdrawn from consideration since they are none-elected invention. Claims 1-5 and 7-29 are examined to the extent of Applicant's elected species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 13- 22, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish (U.S 2003/0054978 A1) in view of Rath (U.S.Patent No. 6,693,129 B2).

Babish teaches composition comprising mixtures of aliphatic alcohol such as **1-tricontanol** and vitamin B12 such as **methylcobalamin** useful for the treatment of cardiovascular arterial disease risk factors such as hypercholesterolemia, hypertriglyceridemia and hyperlipidemia. (abstract, [0017], [0024]-[0030], Table 1, [0039], claims 5, 15). Babish teaches the amount of aliphatic alcohol to be employed is from about 0.001 to 1000mg and can also be within 0.5 to 100mg. (claims 11, 12). This amount is within Applicants amount set forth in claims 13-15. Babish teaches the amount of vitamin B12 such as methylcobalamin to be employed is about 0.0001 to 1000mg. (claim 12). This amount is within Applicants amount set forth in claims 16-20). Babish teaches the composition can be formulated in form of solid capsules, caplets, tablets, softgels, liquids, bars and functional food and other convenient forms such as a solution or suspension, a spray solution. ([0054], claim 14). (see Applicant's claim 29). Babish teaches composition can be further combined with vitamins, minerals, proteins, fats, carbohydrates, natural plant products, and antioxidants. (claim 13). (see Applicant's claim 27). Babish teaches that pharmaceutically acceptable

carriers such as diluents, binders, additives, donating agents, buffers, disintegrants can be employed in the composition. ([0053]. (see Applicant's claim 28).

Babish does not teach the cholecalciferol (Vitamin D3) and Coenzyme Q10 and their amounts effective for the treatment of cardiovascular disease including hyperlipidemia in a single composition.

Rath teaches a composition comprising **cholecalciferol (Vitamin D3)** and **Coenzyme Q10** useful for lowering the risk factors for cardiovascular disease including arteriosclerosis, cerebrovascular disease and hyperlipidemia, by lowering cholesterol, LDL-cholesterol, triglycerides and other metabolic risk factors. (abstract, column 3, paragraphs 3, 4,6 7, Examples). Rath teaches Coenzyme A10 to be employed illustrated with 7mg dosage. (Example 1). This dosage is within Applicant's amounts set forth in claims 21 and 22. Rath teaches cholecalciferol to be employed illustrated with 3.3 mcg. (Example 1). This amount is within Applicant's amount set forth in claims 19 and 20.

It would have been obvious to one of ordinary skill in the art to combine cholecalciferol and coenzyme Q10 to Babish's composition for the treatment of hyperlipidemia because Rath teaches that composition comprising cholecalciferol and coenzyme Q10 and their effective amounts for the treatment of hyperlipidemia. One would have been motivated to combine cholecalciferol and coenzyme Q10 in Babish's composition in order to achieve an expected additive effect of treatment of hyperlipidemia. There is a reasonable expectation of successfully treating hyperlipidemia with the composition of Babish combined with cholecalciferol and

coenzyme Q10 because each of the active agents possesses same effect. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Accordingly, it would be expected that the combination of components would treat hyperlipidemia conditions as well.

Claims 1, 12 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish (U.S 2003/0054978 A1) in view of Gonzales Bravo et al. (U.S.Patent No. 6,486,205 B2).

Babish teaches composition comprising mixtures of aliphatic alcohol such as **1-tricontanol** and vitamin B12 such as **methylcobalamin** useful for the treatment of cardiovascular arterial disease risk factors such as hypercholesterolemia, hypertriglyceridemia and hyperlipidemia. (abstract, [0017], [0024]-[0030], Table 1, [0039], claims 5, 15). Babish teaches the composition can be formulated in form of solid capsules, caplets, tablets, soft gels, liquids, bars and functional food and other convenient forms such as a solution or suspension, a spray solution. ([0054], claim 14). (see Applicant's claim 29). Babish teaches composition can be further combined with vitamins, minerals, proteins, fats, carbohydrates, natural plant products, and antioxidants. (claim 13). (see Applicant's claim 27). Babish teaches that pharmaceutically acceptable carriers such as diluents, binders, additives, donating

agents, buffers, disintegrants can be employed in the composition. ([0053]. (see Applicant's claim 28).

Babish does not teach eicosapentaenoic acid, and docosahexaenoic acid and their amounts effective for the treatment of cardiovascular disease including hyperlipidemia in a single composition.

Gonzales Bravo et al. report that in the last decade, numerous patent have appeared with report the omega-3-poly-unsaturated fatty acids have an effect on serum cholesterol. (column 1, lines 37-67). Gonzales Bravo et al. teach mixtures of fatty acids, especially eicosapentaenoic and docosahexaenoic acids, in daily doses that varies from 500mg/kg of body weight to 0.5-30g is useful in a pharmaceutical formulation as a active agent for treating and lowering cholesterol in blood and for having serum lipid-improving activity. (column 1, line 63- column 2, line 3).

It would have been obvious to one of ordinary skill in the art to combine fatty acids such as eicosapentaenoic acid and docosahexaenoic acid to Babish's comprising mixtures of aliphatic alcohol such as **1-tricontanol** and vitamin B12 such as **methylcobalamin** because the fatty acids such as eicosapentaenoic acid and docosahexaenoic acids are also useful for treating and lowering cholesterol in blood and improving serum lipid activity. One would have been motivated to make such a modification in order to achieve at least an additive effect in treating and lowering cholesterol in hyperlipidemia patient disclosed by Babish. It would be expected that the combination of all components would treat hyperlipidemic conditions as well. The motivation for combining the components flows from their individually known common

utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
March 16, 2007